K090564

510(k) Summary

Submitter's Name:	Truly Intrument Limited
Address:	Truly Industrial Area .ShanWei City. Guangdong Province ,China
Telephone:	86-0660-3380070
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Establishment Registration#: 3003980573

JUN 24 2009

Contact Person:	Manager Yang Jian-Hao
Proprietary Name:	TRULY Infrared Ear Thermometer
Model:	TET-350 TET-360 TET-370
Classification Panel:	General Hospital
Common/Usual Name:	Infrared Ear Thermometer
Product Code :	FLL
Device Classification:	Class II
Contraindications:	N/A
Predicate Device:	Truly Infrared Ear Thermometer TET-350 TET-360 TET-370 is substantially equivalent to Braun IRT 3020,which is sold and in common use in the United States.
Submitted by:	Hu Guo-Chung General Manager Truly Instrument Limited

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2009

Truly Instrument, Limited
Mr. Yang Jian-Hao
Manager
R&D Department
Truly Industrial Area
Shanwei City, Guangdong
CHINA 516600

Re: K090564
Trade/Device Name: Truly Infrared Ear Thermometer, Model TET-350, TET-360 and TET-370
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: May 28, 2009
Received: May28, 2009

Dear Mr. Jian-Hao:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

TRULY®

Truly Instrument Limited

Indication for Use

510(k) Number (if known):

Device Name: Truly Infrared Ear Thermometer

Model:TET-350，TET-360，TET-370

Indication For Use:

The Truly TET-350 TET-360 TET-370 is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal , pediatric and adult population used in the home setting.

Prescription Use ____ OR Over the Counter Use ×

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH:

Division Sign-Off

510(k) K090564

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